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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,732	12/26/2006	Claudia Magagnoli	PP021455.0004 (2300-21455)	5728
27476 7590 07/15/2009 NOVARTIS VACCINES AND DIAGNOSTICS INC. INTELLECTUAL PROPERTY- X100B P.O. BOX 8097 Emeryville, CA 94662-8097			EXAMINER GRASER, JENNIFER E	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 07/15/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,732	Applicant(s) MAGAGNOLI ET AL.	
	Examiner Jennifer E. Graser	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45, 47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 15-42, 47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 43-45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/21/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/30/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-14, 43, 44 (it appears claim 44 was inadvertently left out of the restriction requirement) and 45 in the reply filed on 6/2/09 is acknowledged.

Claims 15-42, 47 and 48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 and 43-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear what is encompassed by a "substantially integral bARE class protein" because the mere recitation of a name, i.e., bARE class protein, to describe the invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence of the protein, the source or molecular weight, which would allow for one to identify the protein without ambiguity. The mere recitation of a name does not adequately define the claimed protein. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in

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and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim 3 is vague and indefinite because it is unclear what is encompassed by 'an analogue thereof' in relation to 'a charged amino acid'. What structure is encompassed by an analogue of an amino acid? The metes and bounds of this language cannot be understood. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim 6 is vague and indefinite because it is unclear what is encompassed by an 'uncharged *agent* or analogue thereof'. First, is this in an 'uncharged stabilizing agent' or a different agent altogether? What structure is encompassed by an analogue of an uncharged agent? The metes and bounds of this language cannot be understood. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim 11 is vague and indefinite because it is unclear what is encompassed by an 'uncharged *agent* " and a "analogue thereof [of a charged amino acid". First, is this

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an 'uncharged stabilizing agent' or a different agent altogether? What structure is encompassed by an analogue of an charged amino acid? The metes and bounds of this language cannot be understood. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim 12 is vague and indefinite because it is unclear what 'integrity ratio' is being referenced. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim Rejections - 35 USC § 112-Scope of Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-14 and 43-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "a composition comprising an isolated LTK63 protein and arginine phosphate and CHAPS", does not reasonably provide enablement for compositions comprising any bARE protein with any stabilizing agent or analogue thereof which is a charged or uncharged amino acid. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification has demonstrated that the particular agents, arginine phosphated and CHAPS work to greatly stabilize the LTK63 protein. The specification has not demonstrated that said agents would be effective in stabilizing any other bARE class protein. The instant specification fails to enable any other composition with an effective stabilizing agent. The prior art (see Wang, W. International J. Pharmaceutics, 199, 185: 129-188; e.g., 'Conclusions') teaches that the stabilization of polypeptides in pharmaceutical areas is unpredictable and that trials and errors play major roles in finding an effective combination. The art is highly unpredictable. The instant claims encompass the use of any bARE protein with any stabilizing agent, any charged amino acid or analog thereof or any uncharged amino acid or analog thereof. The specification does not encompass the scope of these claims. It is unclear what structure is encompassed by an 'analog' of any charged or uncharged amino acid. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly

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need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.”

Given the lack of guidance contained in the specification, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 6-8, 12-14 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Pizza et al (US-A-2002/0044939).

Pizza et al teach compositions comprising substantially integral bARE class proteins and a stabilizing agent which is a zwitterionic agent. The mutated bARE class protein (CT, LT, see paragraph [0030]) is highly stable, i.e., remains substantially integral. Uncharged agents are taught. Pizz et al teach the AB5- LTK63 and LTK 72 proteins. The proteins are analyzed under non-dissociating conditions which differentiate between integral and dissociated bARE class proteins. Immunogenic compositions and methods of treatment are also taught.

8. Claims 1, 2, 6-8, 12-14, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Pronk et al (J.Biochem.Chem. 1985. 260(25): 13580-13584).

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Pronk et al teach compositions comprising substantially integral bARE class proteins and a stabilizing agent which is a zwitterionic agent. Uncharged agents are taught. See the abstract which teaches crystals of LT (a bARE class protein), which crystal is a composition comprising (next to the stabilizing agents CdCl_2 and KF) said bARE class protein in a substantially integral form (see for example, Table II). The term "immunogenic compositions" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

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/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

7/13/09